MAY - 5 2005

510(k) Summary
SKIPPER™ and SKIPPER™ RACE guidewires

510(k) Number: K050756

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter/Contact Person:

Applicant (Manufacturer):	Invatec Innovative Technologies Via Martiri della Libertà, 7 25030 Roncadelle (BS) Italy Tel: +39 030 258 93 11 Fax: +39 030 258 93 12
Submitter's Name:	**ev3** Inc. 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7000 Fax: (763) 398-7200
Official Contact:	Melissa Sommerfeld International Regulatory Affairs Specialist **ev3** Inc. 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7612 Fax: (763) 398-7200 msommerfeld@ev3.net
Summary Preparation Date:	March 22, 2005

Device Name and Classification:

Trade Name:	SKIPPER™ and SKIPPER™ RACE Guidewires
Common Name/Usual Name:	Guidewire
Classification Name:	Catheter, Guidewire
Class:	Class II, 21 CFR 870.1330

Predicate Device:

ev3 Nitrex™ Nitinol Guidewire (K024021, K031864, K040345)

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission.

Device Description:

The SKIPPER and SKIPPER RACE are 0.014" diameter stainless steel guidewires in usable lengths of 175, 195, and 300cm. The guidewires are designed for use in interventional surgical procedures whereby it is introduced percutaneously into the blood vasculature and advanced to a diseased area. The SKIPPER and SKIPPER RACE guidewires contain a silicone or a hydrophilic coating.

Intended Use:
The SKIPPER and SKIPPE RACE guidewires are intended for use in the peripheral and coronary vasculature.

Summary of Testing:
Biocompatibility: Biocompatibility testing in accordance with ISO 10993 Part 1, "Biological Evaluation of Medical Devices," 1997(E) and FDA Memorandum #G95-1, "Biological Evaluation of Medical Devices" was provided.

Performance Data: Bench testing pertaining to performance characteristics was conducted on the SKIPPER and SKIPPER RACE guidewires and compared to the predicate device testing to demonstrate equivalency.

Statement of Equivalence:
The SKIPPER and SKIPPER RACE guidewires are substantially equivalent to the **ev3** Nitrex™ Nitinol Guidewire (K024021, K031864, K040345) in intended use, materials, technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

ev3, Inc.
c/o Ms. Melissa Sommerfeld
International Regulatory Specialist
4600 Nathan Lane North
Plymouth, MN 55442-2920

Re: K050756
SKIPPER and SKIPPER RACE Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (Two)
Product Code: DQX
Dated: March 22, 2005
Received: March 23, 2005

Dear Ms. Sommerfeld:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vuchinich

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K050756

Device Name: SKIPPER™ and SKIPPER™ RACE Guidewires

Indications for Use:

The SKIPPER and SKIPPER RACE guidewires are intended for use in the coronary and peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Bachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050756